K024033

DEC 2 0 2002

SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Applicant:

Olympus Opt-Electronics Co., Ltd.
(New Company Name: AIZU Olympus Co., Ltd.)
500 Aza Muranishi Ooaza Niidera, Monden-machi
Aizuwakamatsu-shi Fukushima, Japan, 965-8520
Registration No.: 9610595

2. Initial Importer

Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11747-3157
Registration No.: 2429304

3. Contact Person

Junko Obata
Olympus Optical Co., Ltd.
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507, Japan
TEL 81-426-42-2891
FAX 81-426-42-2291

B. Device Name, Common Name

1. Trade/Proprietary Name and Common Name

Trade Name: XTJF-160AF DUODENOVIDEOSCOPE
Common Name: DUODENOVIDEOSCOPE

2. Class, Classification Number and Classification Name

CFR Number	Classification Name	Class	Product Code
876.1500	Endoscopes and accessories	II	78-KOG

3. Identification of Legally Marketed Devices Which we Claim Substantial Equivalence

The following listed devices are seem to be as predicate devices in consideration of its characteristic and the following table shows regulatory history.

Model	#510(k)	Manufacturer	Class	Product Code
TJF-140R Duodenovideoscope	#K980465	Olympus Optical Co.,	II	78-KOG
JF-V10 Videoimage Duodenoscope	#K853585	Olympus Optical Co.,	II	78-KOG
EVIS EXERA Colonovideoendoscopes	#K001241	Olympus Optical Co.,	II	78-KOG

C. Summary Description of the Device

1. Summary

This premarket notification is proposed to establish the safety and effectiveness of the variable stiffness scope that is intended for endoscopy and endoscopic surgery, including electrocautery application, within the duodenum. The intended use of the XTJF-160AF is identical to that of previously cleared device, the TJF-140R and JF-V10. The mechanical structure of variable stiffness is identical to that of another predicate device, the EVIS EXERA Colonovideoendoscopes. While the variable stiffness scope is brand new device in the duodenum, endoscopy and endoscopic surgery, including electrocautery, within the duodenum is popular and the mechanical structure of variable stiffness has been confirmed to be safe by the EVIS EXERA Colonovideoendoscopes. Any new insertion method or techniques in consequence of the added mechanical structure of variable stiffness are not considered. Therefore, this modification does not affect the safety and effectiveness of the proposed device.

2. Design

XTJF-160AF has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-2 and IEC60601-2-18.

3. Materials

There are no new patient contacting materials. All of patient contacting materials is cleared by previous 510(k). And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

The XTJF-160AF has been designed to be used with an OLYMPUS EVIS Video System Center, Light Source, Documentation Equipment, Video Monitor, Endo Therapy Accessories (such as a Forceps, Electrosurgical Accessories, etc.), Electorosurgical Unit, and other Ancillary Equipment for endoscopy and endoscopic surgery within the duodenum.

5. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, XTJF-160AF does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Olympus Optical Co., Ltd.
c/o Mr. Donald J. Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
ETL SEMKO
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K024033
Trade/Device Name: XTJF-160AF Duodenovideoscope
Regulation Number: 21 CFR 876.§1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: December 5, 2002
Received: December 6, 2002

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): No assigned yet

Device Name: XTJF-160AF DUODENOVIDEOSCOPE

Indications for Use:

The XTJF-160AF has been designed to be used with an Olympus EVIS video system center, light source, Documentation Equipment, Video Monitor, Endo-Therapy accessories (such as a Forceps, Electrosurgical Accessories, etc.), Electrosurgical Unit, and other Ancillary Equipment for endoscopy and endoscopic surgery within the duodenum.

Do not use these instruments for any purpose other than their intended uses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lagnn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024033